GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:422
ANSWERED ON:07.07.2004
SPURIOUS AND BANNED DRUGS IN CIRCULATION
Athawale Shri Ramdas;Jagannath Dr. M.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the total number of cases of sale of spurious, outdated and banned drugs brought to the notice of the Government during the Eighth, Ninth and Tenth Plan period;

(b) whether the number of such cases is on the increase especially in Metros during the last three years;

(c) if so, the details thereof; and

(d) the remedial measures being taken/proposed to be taken to check this menace?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (c): As per the feedback available from State Drugs Controllers, 36947, 38824 & 36314 drug samples were tested during the period 2000-2001, 2001-2002 & 2002-2003 out of which 112, 96 and 125 samples respectively were found spurious which is 0.3, 0.25 and 0.34% of the samples reported spurious for the last three years. Thus, it does not appear that there is increase in the number of such cases of spurious drugs during the said period. So far as cases of sale of outdated/banned drugs is concerned, no case of sale of such drugs was reported during the said period.

(d): Under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder, the responsibility for regulating manufacture and sale of drugs including monitoring their quality is vested with the State Govts. The State Govts. are advised from time to time to gear up their enforcement machinery to detect and unearth spurious/fake drugs moving in the inter-state commerce as well as to provide and strengthen their regulatory infrastructure; to establish their own State level testing labs. To ensure speedy analysis of drug samples for which they are provided assistance to strengthen and augment infrastructure facilities in the State Labs. The State Govts. have also been advised to keep strict surveillance over the suspected dealers; collect of survey samples under NSQD programme; constitute/reactivate State drug advisory committees in which various trade and industry association as well as consumer associations can file representations; establishment separate intelligence-cum-legal cell; develop efficient communication facilities and recall procedures; engage experienced counsel for fighting spurious drug cases etc.

Since manufacture and sale of spurious drugs is mainly a clandestine activity indulged in by anti-social persons, steps are taken from time to time by enforcement authorities of the States to detect and unearth spurious drugs in the inter-state commerce. Govt. of India has taken the following initiatives to tackle the problem of spurious drugs:-

i) Detailed guidelines in respect of strategies required to be adopted for efficient surveillance over the movement of spurious drugs were also communicated to the State Government, in November 17, 1999 to ensure focused surveillance over manufacture and sale of spurious drugs.

ii) Issues concerning alleged sale of spurious drugs was taken up by Union Health Minister with State Health Ministers in the 7th Conference of Central Council of Health (CCH) &FW held on 12 - 13 July, 2001. CCH resolved that in order to address issues relating to the increasing reports of spurious drugs / counterfeit drugs, special attention requires to be given to monitor and unearth such illegal activities by constituting a separate intelligence-cum-legal cell in the respective drug control organizations and in seeking cooperation of the pharma industry, trade as well as the police.

iii) Department of Health Government of India constituted a broad based Committee under the Chairmanship of Director General of Health Services (DGHS) in July, 2001 to examine issues concerning the problem of spurious drugs. The observations and recommendations of this Committee have been circulated on Sept.16, 2002 to all State Drugs Controllers for their information and necessary action in the matter.

iv) Union Minister of Health & Family Welfare had specifically written to all Chief Ministers on Oct.8, 2002 on the issue of spurious drugs, seeking their personal intervention to ensure that adequate measures are taken in each State to vigorously pursue the strategies needed to preclude any possibility or menace of spurious products so as to collectively ensure its total eradication.

v) A meeting of Health Ministers and Senior Officials of 13 major States of the country was convened by Union Minister or Health & Family Welfare on 12.11.2002 to ensure concerted action to check any possible movement of spurious drugs in the country and to involve all stake holders to fight this menace. Suggestions/views which emerged out of discussion were forwarded on Jan.8,2003 to

all the State Govts. for their information and necessary action. One of the outcome of the said discussion, was enactment of `The Gujarat Prevention of Anti-social Activities Act,1985 (PASA)` by the State Govts. for deterrent action against offenders.

vi) In order to increase the number of drug samples tested in the country and to bring down the reporting time to less than a month as against 3 to 6 months presently being taken by many laboratories, a comprehensive plan has been undertaken by Central Govt. under a capacity building project through World Bank assistance.

vii) In order to ensure speedy information exchange and networking of all States and Central Drugs Control Offices and Laboratories, computerization project has been undertaken by Central Govt.

viii) A specialized training programme for drugs control officers of all State Govts. responsible for keeping surveillance over possible movement of spurious drugs has been formulated and was conducted from 24-27 June, 2003 by Central Govt. in cooperation with FDA, Maharashtra at Mumbai. 26 drugs control officers from different States had attended the training programme at FDA, Mumbai on investigational skills.

ix) The Govt. of India has set up an expert committee on January 27, 2003 under the Chairmanship of Dr.R.A.Mashelkar, DG, CSIR and Secretary to Govt. of India to look into the various issues related to Drugs Control Administration as well as to estimate the extent of the problem of spurious drugs and recommend measures to deal with this problem effectively. On the basis of the recommendations contained in the report of the Committee, a Drugs and Cosmetics (Amendment) Bill, 2003 was introduced in the Lok Sabha on 22nd December, 2003 for making the penal provisions in the Act in order to make them more stringent.